## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

WUHAN HEALTHGEN BIOTECHNOLOGY CORPORATION, et al.

Plaintiffs / Counterdefendants,

C.A. No. 24-318-RGA

v.

EXPRESSTEC LLC, et al.

Defendants / Counterclaimants.

<u>LETTER TO THE HONORABLE RICHARD G. ANDREWS FROM PLAINTIFFS</u>
<u>REGARDING PROTECTIVE ORDER DISPUTES</u>

Dear Judge Andrews,

Healthgen submits this letter regarding three disputes in the parties' Proposed Protective Order ("PO").¹ Defendants' proposals to include a third, heightened category of designation, HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY – SPECIAL HANDLING ("AEO-Special Handling"), and to restrict access to such material based on U.S. citizenship and residency status of attorneys/experts, should be rejected. The agreed-upon provisions of the PO, coupled with Plaintiffs' proposed restrictions on who can access the highly sensitive information, provide numerous, stringent protections that safeguard the parties' information. Defendants' proposals also needlessly depart from protective orders usually entered in cases involving similar technologies in this District. Additionally, Plaintiffs' proposal to limit access to specific individuals who are not otherwise involved with competitive decision-making activities achieves a reasonable compromise to protect both parties' highly sensitive information. Healthgen respectfully requests that the Court adopt its proposals and reject Defendants' proposals as reflected in Ex. 1.

Defendants' Heightened Restrictions for AEO-Special Handling Are Unwarranted: Defendants propose a third category, in addition to "CONFIDENTIAL" and "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY" ("AEO") designations, with more restrictive special handling requirements for outside counsel, consultants, and experts. Ex. 1 ¶¶ 6, 7, 8(a), 8(c), 8(d), 17(a)-(h), 22, and 29. Defendants, the parties seeking the more restrictive provisions, have failed to meet their burden to show these restrictions are necessary. See In re Deutsche Bank Tr. Co. Ams., 605 F.3d 1373, 1378 (Fed. Cir. 2010).

The agreed-upon provisions, in conjunction with Plaintiffs' proposed language to reasonably limit access to designated information, provide significant protections to safeguard the parties' highly sensitive information. The parties have already agreed to protect the identical category of information such as formulations, manufacturing information, research and development records, basic non-public research, etc., as AEO protected material. Compare Ex. 1 ¶ 5 with ¶ 6. Further, it is agreed that "Designated Information under this Protective Order may be used only by persons permitted access to such information under this Protective Order" and "shall be used by the Receiving Parties only for purposes of this Action." *Id.* ¶ 10. The parties have also agreed that before any designated information is disclosed, individuals such as experts must be identified under the applicable provisions. Id. ¶¶ 19-20. In addition, the PO protects against inadvertent disclosure of confidential information that a fact witness would otherwise not be privy to. Id. ¶ 21. The PO further requires that a "recipient of any Designated Information that is provided under this Protective Order shall maintain such information in a secure and safe area and shall exercise reasonable and proper care with respect to the storage, custody, use, and/or dissemination of such information." *Id.* ¶ 24. And the PO requires destruction or return of designated information after the final termination of this action. *Id.* ¶ 39. Defendants fail to explain why these safeguards are inadequate.

Defendants' proposed restrictions for "AEO-Special Handling Material" will only burden the parties with unnecessary expenses and inefficiencies. Indeed, Defendants acknowledge this is an "extraordinary protection." Id.  $\P$  6. Defendants propose, for example, limiting access to any AEO-Special Handling Material to "stand-alone computers' . . . not [] linked to any network, including a local area network ("LAN"), an intranet or the Internet[] located at the offices of the

<sup>1</sup> The specific paragraphs that contain contested language are  $\P$  6, 7, 8(a), 8(c), 8(d), 16(a)-(c), 17(a)-(h), 22, and 29.

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Producing Party's outside counsel of record" (*id.* ¶ 17(a)). Such a restriction would require outside attorneys, consultants, and/or experts to make multiple visits to the offices of the Producing Party's outside counsel of record as discovery proceeds. Defendants further propose prohibiting the creation of "electronic copies of Special Handling Material . . . without prior written consent of the Producing Party" (*id.* ¶ 17(e)); requiring "[t]he Receiving Party [of Special Handling Material] . . . maintain a log of all such files that are printed or photocopied (*id.* ¶ 17(f)); and prohibiting "[t]he Receiving Party [from printing] more than 250 pages" (*id.*). These restrictions would necessarily complicate discovery without any added benefit as the same information would otherwise be protected as AEO materials under the agreed upon provisions.

Defendants' assertion that the heightened restrictions are needed to protect their product development and manufacturing related information lacks substantial support. *First*, Defendants' stated basis is belied by the parties' prior litigation history involving similar subject matter in which the protective order did not contain such restrictions. ITC Action No. 337-TA-1238 ("ITC Action"). Under the ITC Action protective order, the parties agreed to protect "Confidential business information [] which concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures [] or other information of commercial value" without any of the special handling restrictions Defendants propose here. Ex. 2 ¶¶ 1-3. Defendants produced information related to the accused products such as Optibumin, financial, marketing, and other information in the ITC Action. *See*, *e.g.*, D.I. 31-1, Ex. 14. *Second*, Defendants' proposed restrictions deviate significantly from protective orders used for biotechnology matters in this District. *See*, *e.g.*, Exs. 3-5. Instead, they mirror requirements for source code review, which is not at issue in this litigation. *See* Delaware Default Standard for Access to Source Code. Defendants' proposal should be rejected.

Defendants' Blanket Restriction Based on Immigration Status and Nationality Is Unjustified: This Court should reject Defendants' proposal that AEO and AEO-Special Handling Material "may not be transmitted by the Receiving Party to any person or entity outside the United States without the consent of the Producing Party" and that access to AEO-Special Handling Material be restricted to "U.S. citizen[s] and resident[s] of the United States." Ex. 1 ¶ 17 and 17(c). At the outset, Defendants have not met their burden to show that a categorical restriction based on immigration and nationality is warranted here. See In re Deutsche, 605 F.3d at 1378. In fact, in the ITC Action, Defendants produced highly sensitive materials related to the same products accused in this case (see, e.g., D.I. 31-1, Ex. 14) without a blanket restriction based on immigration or nationality in the ITC protective order. Ex. 2. To the extent Defendants have concerns about any particular expert, the agreed-upon provisions in the PO already require experts to execute an undertaking to comply with the PO and provide Defendants the opportunity to object in good faith before any confidential information is disclosed. Ex. 1 ¶¶ 19, 20(a)-(c); see also Ex. 6, Intell. Ventures I LLC, v. AT&T Mobility LLC, C.A. No. 12-193-LPS, D.I. 126 (D. Del. Dec. 16, 2013) (granting "Plaintiffs' request to share confidential information with experts and consultants located outside the United States" on the condition that "it is for the purpose of assisting in the litigation of this action" and such individuals would comply with the protective order).

Additionally, the proposed blanket nationality restriction does not incrementally protect Defendants' designated information any more than the agreed-upon provisions in the PO. Instead, it unfairly hampers Plaintiffs, two foreign corporations based in China, from asserting their claims and defenses in this litigation by restricting who Plaintiffs can retain as counsel, experts, and

vendors. See Ex. 7, S.I.SV.EL. Societa Italiana Per Lo Sviluppo Dellelettronica S.p.A v. Rhapsody Int'l, Inc., C.A. No. 18-069-CJB, D.I. No. 58 (D. Del. Nov. 5, 2019) (rejecting nationality-based protective order provision because it was "too restrictive" and "the Court [did] not wish to restrict the pool of possible experts [for Plaintiff to retain] any further"). Further, Defendants' proposed requirement to seek their consent before transmitting any AEO or AEO-Special Handling Material to "any person or entity outside the United States" is unnecessary given the PO's threshold disclosure requirements and improper because it would reveal Plaintiffs' litigation strategy. Bos. Sci. Corp. v. Edwards Lifesciences Corp., C.A. No. 16-275-SLR-SRF, 2016 WL 7440473, at \*2 (D. Del. Dec. 27, 2016) (denying protective order procedure requiring notice prior to disclosure of protected material as it would reveal attorneys' work product privileged information). Last, the nationality restriction is particularly prejudicial here because Defendants' proposal restricts Plaintiffs to a single outside consultant or expert who is a "U.S. citizen and resident" for all four patents-in-suit. Ex. 1 ¶ 17(c). Even in cases involving source code review where jurisdictional limits are sometimes imposed, this District has recently held that such categorical nationality restrictions for individuals are unwarranted. Ex. 8 at 14:21-23 (adopted by Multifold Int'l, Inc. v. Motorola Mobility, LLC, C.A. No. 23-1173-JLH, D.I. No. 44 (D. Del. June 14, 2024); Ex. 7 (rejecting restriction of confidential information from being "released to any foreign national (even if within the United States)"). Defendants' blanket restriction should similarly be rejected here.

Plaintiffs' Proposal to Preclude Certain Individuals Is Reasonable: Plaintiffs' proposal that designated information is disclosed only to individuals who are otherwise not involved in competitive decision-making activities are appropriate and necessary here. Ex. 1 ¶ 16(a)-(c). In particular, Plaintiffs propose that outside counsel of record with access to CONFIDENTIAL and AEO (and AEO-Special Handling under Defendants' proposal) materials are limited to those who are not involved in patent prosecution, regulatory communications, and business competitive decision-making relating to recombinant human serum albumin (rHSA) products. *Id.* ¶ 16(a). These limitations are justified here as there is no dispute that the parties are direct competitors in the rHSA field. Further, an attorney from Hovey Williams (Defendants' outside lead counsel firm) is identified as a member of the "Management Team" on Defendants' website, akin to an in-house attorney. Ex. 9 ("Crissa is a U.S. Patent Attorney and serves as outside counsel for InVitria. She advises InVitria on every aspect of its intellectual property, including all domestic and foreign patent and trademark matters, related contracts, due diligence matters, enforcement, and dispute resolution. Crissa is a Partner with Hovey Williams LLP") (emphasis added). In addition, attorneys at Hovey Williams are the prosecution attorneys for Defendants' asserted patent. D.I. 13, Ex. A. Plaintiffs have proposed a prosecution and regulatory bar for in-house attorneys and party representatives who will have access to Plaintiffs' CONFIDENTIAL information for similar reasons. Ex. 1 ¶ 16(b)-(c). As this Court has acknowledged, "once such confidential information is disclosed, the bell cannot be unrung." See Blackbird Tech LLC v. Serv. Lighting & Elec. Supplies, Inc., C.A. No. 15-53-RGA, 2016 WL 2904592, at \*5 (D. Del. May 18, 2016); see also, Affymetrix, Inc. v. Illumina, Inc., C.A. No. 04-901-JJF, 2005 WL 1801683, at \*2 (D. Del. July 28, 2005) (precluding one in-house counsel since she "is part of [defendant's] management team and is involved with settling patent litigation and licensing"). Moreover, Defendants will not be prejudiced as they can continue to engage outside attorneys from Hovey Williams and Morris, Nichols, Arsht and Tunnel who do not fall under the exclusionary criteria. Ex. 1 ¶ 11(d). As "there is a concrete, particularized risk of inadvertent disclosure and misuse" of Plaintiffs' confidential information here, this Court should adopt Plaintiffs' proposed language. Blackbird Tech LLC, 2016 WL 2904592, at \*5.

## Dated: July 2, 2024

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